



**Billing Code 6355-01-P**

**CONSUMER PRODUCT SAFETY COMMISSION**

**16 CFR Parts 1112 and 1222**

**Docket No. CPSC-2012-0067**

**Safety Standard for Bedside Sleepers**

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Final rule.

**SUMMARY:** The Danny Keysar Child Product Safety Notification Act, Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is issuing a safety standard for bedside sleepers in response to the direction under Section 104(b) of the CPSIA.

**DATES:** The rule is effective on July 15, 2014. The incorporation by reference of the publication listed in this rule is approved by the Director of the *Federal Register* as of [INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Daniel Dunlap, Compliance Officer, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301-504-7733; e-mail: [ddunlap@cpsc.gov](mailto:ddunlap@cpsc.gov).

## **SUPPLEMENTARY INFORMATION:**

### **A. Background and Statutory Authority**

The Consumer Product Safety Improvement Act of 2008, (CPSIA, Pub. L. 110-314), was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission to: (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts, and (2) promulgate consumer product safety standards for durable infant and toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

The term “durable infant or toddler product” is defined in section 104(f)(1) of the CPSIA as a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years. Bassinets and cradles are specifically identified in section 104(f)(2)(L) as durable infant or toddler products. Bedside sleepers are similar to bassinets, and many bedside sleepers also function as bassinets. In addition, some bedside sleepers are accessories to play yards, which are explicitly identified in section 104(f)(2)(F).

On December 10, 2012, the Commission issued a notice of proposed rulemaking (NPR) for bedside sleepers (77 FR 73345). The NPR proposed to incorporate by reference the voluntary standard, ASTM F2906-12, “Standard Consumer Safety Specification for Bedside Sleepers,” with certain changes to provisions in the voluntary standard to strengthen the ASTM standard.

In this document, the Commission is issuing a safety standard for bedside sleepers. Pursuant to Section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this proposed standard, largely through the ASTM process. The rule incorporates the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2906-13, “Standard Consumer Safety Specification for Bedside Sleepers” (ASTM F2906-13), by reference, and requires bedside sleepers to be tested to 16 CFR part 1218, the Safety Standard for Bassinets and Cradles (bassinet standard).

## **B. The Product**

ASTM F2906-13 defines “bedside sleeper” as “a rigid frame assembly that may be combined with a fabric or mesh assembly, or both, used to function as sides, ends, or floor or a combination thereof, and that is intended to provide a sleeping environment for infants and is secured to an adult bed.” A “multi-mode product” is “a unit that is designed and intended to be used in more than one mode (for example, a play yard, bassinet, changing table, hand held carrier, or bedside sleeper).” A bedside sleeper is intended to be secured to an adult bed to permit newborns and infants to sleep close by an adult without being in the adult bed. Bedside sleepers currently on the market have a horizontal sleep surface that typically is 1 inch to 4 inches below the level of the adult bed’s mattress. The side of the bedside sleeper that is adjacent to the adult bed can usually be adjusted to a lower position, a feature that differentiates bedside sleepers from bassinets, where all four sides of a bassinet are the same height. Current bedside sleepers range in size from about 35” x 20” to 40” x 30.” Bedside sleepers may have rigid sides, but they are most commonly constructed with a tube frame covered by mesh or fabric. Bedside sleepers are intended for use with children up to the developmental stage where

they can push up on hands and knees (about 5 months). This is the same developmental range for the intended users of bassinets.

Several manufacturers produce multiuse (or multimode) bedside sleeper products that can convert into bassinets and/or play yards. Most bedside sleeper products can be converted into a bassinet by raising the lowered side to create four equal-height sides, and a few also convert into both a bassinet and play yard. Some play yards include bedside sleeper accessories, which when attached, convert the play yard into a bedside sleeper; and some bassinets convert into bedside sleepers. All of the tube-framed products that CPSC staff has evaluated may be collapsed for storage and transport. A bedside sleeper that can be used in additional modes would need to meet each applicable standard. For example, a bedside sleeper that converts to a bassinet must meet the bedside sleeper standard and the bassinet standard.

### **C. Incident Data**

The preamble to the NPR summarized the incident data involving bedside sleepers reported to the Commission from January 2001 through December 2011. 77 FR 73345 (December 10, 2012). The data was extracted on January 24, 2012. CPSC's Directorate for Epidemiology staff identified 40 cases of bedside sleeper-related incidents from 2001 to 2011, including four fatalities and 36 nonfatal incidents (with and without injuries). Since the NPR, the incident data have been updated to include bedside sleeper-related incident data reported to the Commission between January 24, 2012 and May 15, 2013.

Since the extraction of the data presented in the NPR, CPSC staff has received four new reports involving bedside sleepers. One of the reports was a consumer query regarding a recalled product and did not involve an actual incident. The rest of the reports involved no fatalities or injuries. The infants identified in the incident reports ranged in age from 1 to 6 months.

The hazards reported in the new incidents were consistent with the hazard patterns identified among the 40 incidents presented in the NPR briefing package. The hazard scenarios reported in 24 of the 40 incidents (60 percent) were attributed to some sort of failure/defect or a potential design flaw in the product.

Among the four new reports, two incidents were classified under *miscellaneous product-related issues* concerning the *poor design* and a *broken/detached component* of the product. In the incident reporting poor design, the consumer expressed concern that the fabric side could create a suffocation hazard when the child's face is against the fabric; the consumer reportedly stopped using the product. The second incident involved a six-month-old who fell onto the floor from a recalled, multimode product when the horizontal bar that converts the product from a bedside sleeper to a bassinet, broke off or detached. No injury was reported, and it is unclear whether the consumer was aware of the recalled status of the product. The third incident is categorized as an *assembly instruction issue*, where it appears that the consumer did not properly follow the assembly instructions. The last report was a *CPSC recall-related consumer query*; no actual incident was involved.

#### **D. Overview of ASTM F2906**

ASTM first published a voluntary standard for bedside sleepers, ASTM F2906-11, in December 2011. ASTM F2906 specifically addressed hazards associated with bedside sleepers, including incidents involving the creation of a hazardous gap between the product and an adult mattress, by requiring the successful completion of three disengagement tests. The tests help ensure that the securing components can withstand forces that may be exerted on the product by either the child or an adult, while sleeping. The gap must be no more than 0.5 in. when the product is installed onto the adult bed, per each manufacturer's directions. When a 25-lb.

horizontal force is applied near the attachment system or corners, the gap may not exceed 1.0 in. To simulate an adult rolling into a bedside sleeper while sleeping, a gap greater than 1.0 in. may not be created after the application and release of a 50-lb. horizontal force to the bedside sleeper's corners. The inclusion of these anti-gap requirements serve to mitigate the foreseeable head and neck entrapment hazards posed by bedside sleepers. In addition, bedside sleepers must also satisfy the minimum side-height requirement for bassinets (the upper surface of the non-compressed mattress of a bassinet/cradle must be at least 7.5 inches lower than the upper surface of the lowest side in all intended bassinet/cradle use positions), with the exception of the lowered side rail (the height of the side rail in the lowest position shall be no less than 4 inches when measured from the top of the uncompressed bedside sleeper mattress to the top of the lowered side rail, when the mattress support is in its highest position).

Bedside sleepers and bassinets share a significant number of hazard patterns because both products are intended to be used by children with the same developmental abilities and for the same purpose. Many bedside sleepers also function as bassinets. Accordingly, the bedside sleepers voluntary standard requires bedside sleepers to be tested to the bassinet standard (ASTM F2194).

### **1. Proposed Rule**

In the NPR, CPSC identified 24 incidents attributed to defect or potential design flaws in bedside sleepers. The hazards associated with these incidents included: issues with the adjustable fabric cover over the metal bars on the side that lowered in the bedside sleeper mode (9 incidents); poor assembly instruction (6 incidents); and miscellaneous other product-related issues (9 incidents). To address these incidents, the Commission proposed in the NPR to adopt by reference, ASTM International's voluntary standard, ASTM F2906-12, *Standard Consumer*

*Safety Specification for Bedside Sleepers*, with a few additions to strengthen the standard. ASTM F2906-12 also required that, in addition to the tests provided in ASTM F2906-12, the bedside sleeper must be tested to the bassinet standard (ASTM F2194). Additionally, multimode products must also be tested to each applicable standard associated with the product's use modes.

In the NPR, the Commission proposed adding clarifying language to ASTM F2906-12 so that the hazards associated with play yard bassinet misassembly and fabric-sided enclosed openings would also be addressed in bedside sleepers for bedside sleeper accessories. As discussed in the preamble to the NPR, for bassinets/cribels with fabric sides, a fully bounded opening may not be created that allows the complete passage of the torso probe (based on a torso diameter of a 5th percentile, 0 to 2-month-old infant) when tested in accordance with the fabric release test methods for enclosed openings. However, the test does not apply to play yard bassinet accessories. Bassinet accessories to play yards (that cannot be converted to bedside sleepers) are usually held in place by fasteners that clip to the top of the play yard's railing. If the fasteners were left unclipped, the bassinet would fall, rendering the product untestable, due to the complete collapse of the bassinet attachment. Unlike bassinet play yard accessories, a bedside sleeper play yard accessory could have fasteners left unclipped (through the detachment of snaps/Velcro<sup>®</sup>) where the bedside sleeper with the lowered side does not completely collapse and appears functional. As a result, the Commission determined that all bedside sleeper play yard accessories should be subject to the requirements of the bassinet standard's fabric-sided enclosed openings test (without the exemption for bassinet play yard accessories), given the entrapment and suffocation hazards presented when a bedside sleeper's removable cover (liner or shell) is either not used or not secured properly.

To address this hazard, the Commission proposed to add a new definition for “bedside sleeper accessory” and eliminate the fabric-sided, bounded-opening performance requirement exemption currently granted to play yard bassinet accessories. The definition proposed was: “bedside sleeper accessory, n – an elevated sleep surface that attaches to a non-full-size crib or play yard, designed to convert the product into a bedside sleeper intended to have a horizontal sleep surface while in a rest (non-rocking) position.” In addition, the Commission proposed to add a new section: “Bedside Sleeper Accessory Fabric-Sided Enclosed Openings—A bedside sleeper accessory shall meet the F2194 performance requirement “Fabric-Sided Enclosed Openings.” However, a bedside sleeper would be exempt from this requirement if the bedside sleeper collapsed under its own weight or the sleep surface tilts by more than 30 degrees.

The Commission also proposed additional language to address play yard bedside accessory misassembly. The Commission had already proposed a requirement to address consumer misassembly of key structural elements for bassinet accessories to play yards in the play yard standard, ASTM F406. However, the proposed play yard standard did not include specific language for a misassembled bedside sleeper accessory. Accordingly, the Commission proposed to add a new section to include bedside sleepers: “Bedside Sleeper Play Yard Accessories Missing Key Structural Elements: A bedside sleeper accessory shall meet the F406 general requirement “Bassinet/Cradle Accessories Missing Key Structural Elements.”

## **2. Recent Developments in the Play Yard Standard and Bassinet Standard**

After the the Commission published the NPR for bedside sleepers in the *Federal Register*, the ASTM play yard subcommittee worked closely with the ASTM bassinet subcommittee to address hazards related to bassinet accessory misassembly. The subcommittees decided to address the hazards associated with bassinet accessory misassembly in two different



ASTM standards: (1) the play yard standard, ASTM F406-13, *Standard Consumer Safety Specification for Non-Full-Size Baby Cribs/Play Yards*, now addresses safety issues related to bassinet accessory attachment components (*i.e.*, structures that attach the bassinet accessory to the play yard); and (2) the bassinet standard, ASTM F2194-13, *Standard Consumer Safety Specification for Bassinets and Cradles*, addresses safety issues related to mattress support rods (and all other structures that ensure that the bassinet accessory mattress is flat and stable) through the segmented mattress-flatness test contained in the bassinet standard. These requirements are now part of the current ASTM standards for play yards, ASTM F406-13, and for bassinets/cradles, ASTM F2194-13.

On August 19, 2013, the Commission issued an amendment to the *Safety Standard for Play Yards*, to incorporate by reference the most recent version of ASTM's play yard standard, ASTM F406-13, to address the hazards associated with misassembly of play yard bassinet accessories. 78 FR 50328. The play yard standard, ASTM F406-13, now addresses safety issues related to bassinet accessory attachment components (*i.e.*, structures that attach the bassinet accessory to the play yard).

On October 23, 2013, the Commission issued a final rule for bassinets, *Safety Standard for Bassinets and Cradles*, to incorporate by reference the most recent version of ASTM's bassinet standard, ASTM F2194-13, to address safety issues related to mattress support rods (and all other structures that ensure that the bassinet accessory mattress is flat and stable) through the segmented mattress-flatness test contained in the bassinet standard. 78 FR 63019. In addition, the Commission's bassinet rule required several modifications to ASTM F2194-13. These modifications:

- added new definitions, a test requirement, and test procedure for a new performance requirement pertaining to the stability of bassinets with removable bassinet beds;
- revised the current stability test procedure by specifying the use of a newborn CAMI dummy, rather than the six-month infant CAMI dummy;
- revised the pass/fail criterion for the segmented mattresses flatness test to make it more stringent;
- excluded segmented mattress flatness test bassinets that are less than 15 inches wide along the width of the mattress; and
- revised the scope to clarify that a multimode or combination product must meet the requirements of all standards associated with its use modes.

These additional requirements are codified at 16 CFR part 1218, *Safety Standard for Bassinets and Cradles*.

### **3. Current ASTM Bedside Sleeper Standard (ASTM F2906-13)**

The current version of the voluntary standard for bedside sleepers adopts the same performance requirement and test method in ASTM's play yard standard, ASTM F406-13, which addresses the hazards associated with misassembly of play yard bassinet accessories, for bedside sleeper accessories. To provide clearer definitions of a "bedside sleeper accessory," ASTM F2906-13 now provides definitions for "bedside sleeper accessory" and "bedside sleeper accessory attachment components." ASTM F2906-13 provides that a bedside sleeper accessory is an elevated sleep surface that attaches to a play yard designed to convert the product into a bedside sleeper and is intended to have a horizontal sleep surface while in a rest (non-rocking)

position. Bedside sleeper accessory attachment components are defined as components that provide the means of attachment for a bedside sleeper accessory to a play yard.

ASTM F2906-13 also adds a definition of a “bedside sleeper shell.” As explained in the NPR, there are demonstrated hazards presented when a bedside sleeper’s removable cover, including a liner or shell, is either not used or not secured properly. 77 FR 73348-49.

Accordingly, “bedside sleeper shell” is defined as a textile cover for bedside sleeper accessory that incorporates structural elements such as tubing, permanently attached clips or hooks, or other elements that allow it to be suspended from the play yard frame.

In addition, ASTM F2906-13 addresses the hazards associated with misassembly of play yard bedside sleeper accessories. The standard adopts the same requirements set forth in ASTM F406-13 for bassinet/cradle accessories missing accessory attachment components, and an associated test method for misassembly failure under the bassinet/cradle accessory sleep surface collapse/tilt test. Under the current ASTM F2906-13 standard, bedside sleeper accessories must have all accessory attachment components permanently attached to the bedside sleeper accessory. If bedside sleeper accessories that require consumer assembly of accessory attachment components can be assembled and attached to the product with any accessory attachment component missing, the accessory must either: (1) collapse such that any part of the mattress pad contacts the bottom floor of the play yard or is not able to support 4.0 lbm test mass tested; or (2) the bedside sleeper accessory sleep surface must tilt by more than 30 degrees when tested to the bedside sleeper accessory sleep surface collapse/tilt test.

ASTM F2906-13 also continues to require bedside sleepers to meet the requirements of the bassinet standard, ASTM F2194, with the exception of the height of the lowered fourth side. Most bedside sleepers also function as bassinets. The intended users are identical, and the

majority of the hazards are identical. Because bedside sleepers are already required to be tested to the bassinet standard, ASTM F2194, all of the requirements and test methods in ASTM 2194 are not restated in the bedside sleeper standard ASTM F2906-13. However, ASTM F2906-13 specifically adds a new section on fabric release test methods for enclosed openings for bedside sleeper accessories. As stated above, although the bassinet standard, ASTM F2194, contains a requirement for fabric-sided enclosed openings, the test does not apply to play yard bassinet accessories. Bassinet accessories to play yards (that cannot be converted to bedside sleepers) are usually held in place by fasteners that clip to the top of the play yard's railing. If the fasteners were left unclipped, the bassinet would fall, rendering the product untestable, resulting in test failure. However, the unique hazard associated with bedside sleepers requires testing for fabric-sided enclosed openings because bedside sleepers have a lowered fourth side that can create a hazard when the removable cover or shell is either not used or not secured properly. ASTM F2906-13 addresses this hazard by making explicit that the fabric release test methods for enclosed openings apply to all bedside sleepers and bedside sleeper accessories.

In this rule, the CPSC incorporates by reference ASTM F2906-13 because the Commission's proposed modifications in the NPR have been adopted in ASTM F2906-13, including the requirements and test methods for bedside sleeper accessories missing accessory attachment components and bedside sleeper accessory fabric-sided enclosed openings. In addition, because bedside sleepers are required to be tested to the bassinet standard, and because the Commission recently issued a mandatory standard for bassinets (incorporating the ASTM bassinet standard with modifications), which was codified at 16 CFR part 1218, the Commission adopts ASTM F2906-13 with revisions to change the references to the voluntary bassinet

standard, ASTM F2194, in the standard with references to the mandatory bassinet standard, 16 CFR part 1218.

## **E. Response to Comments**

The Commission received five comments in response to the NPR from consumers, industry, consumer advocacy groups, and trade associations. A summary of each comment topic and response is provided.

### **1. General comments**

**Comment:** One commenter generally supported the proposed rule. Another commenter stated that the responsibility for the safe use of products lies with the parent of the young child.

**Response:** Section 104 of the CPSIA requires the Commission to examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products and to promulgate mandatory standards. The Commission has identified bedside sleepers as a durable infant or toddler product. Bedside sleepers are similar to bassinets and function also, in many instances, as bassinets. The Commission has concluded that more stringent requirements would further reduce the risk of injury associated with the product. Accordingly, the Commission is issuing a safety standard for bedside sleepers in response to the direction under section 104 of the CPSIA.

### **2. Mandatory standards should be finalized**

**Comment:** Several commenters stated that the standards for play yards and bassinets should be finalized, including the issues related to fabric-sided enclosed openings and consumer misassembly with missing components before they are applied to bedside sleepers. In addition, two commenters stated that to avoid confusion, the specific requirements of ASTM F406 and

ASTM F2194 should be inserted into ASTM F2906, rather than simply referencing those standards.

**Response:** ASTM has finalized both the play yard standard, ASTM F406-13, and the bassinet standard, ASTM F2914-13. The Commission has made some additional modifications to ASTM F2194-13. The requirements for fabric-sided enclosed openings have been adopted in ASTM F2906-13 for bedside sleeper accessories. The requirements for misassembly of play yard bassinet accessories have also been adopted in ASTM F2906-13 for bedside sleeper accessories. Those provisions have been included in ASTM F2906-13.

ASTM's bedside sleeper standard, ASTM F2906-13 did not include all the modifications that the Commission subsequently made to the CPSC bassinet standard. Therefore, the final rule for bedside sleepers requires reference to 16 CFR part 1218 to reflect those modifications.

### **3. Redundant product safety feature**

**Comment:** One commenter stated that the play yard bassinet accessory misassembly requirement may compel manufacturers to eliminate redundant safety features that are already a component of the product. The commenter stated that removal of the mattress pad support bars does not replicate or address the misassembly incident or result in a safer product.

**Response:** This comment has been addressed in the Commission's final safety standards for play yards and for bassinets and cradles. The play yard standard, ASTM F406-13, addressed safety issues related to bassinet accessory attachment components (*i.e.*, structures that attach the bassinet accessory to the play yard). The bassinet standard, ASTM F2194-13, addressed the issue of mattress pad support rods (and all other structures that keep the bassinet accessory mattress flat and stable) through the segmented mattress flatness test. ASTM F2194-13 now requires that bassinets with removable mattress support rods be tested both with and without the

mattress support rods. In addition, the Commission's modifications to ASTM F2194 in the final rule for the safety standard for bassinets included a change to the pass/fail criterion for the mattress flatness test and revisions to the stability test procedures for bassinets. These safety features are not redundant because each product must meet the standards associated with the product's use mode. 78 FR 50332 and 63025.

#### **4. Intellectual property**

**Comment:** One commenter stated that there may be patents that restrict options for manufacturers. For example, the commenter stated that there is a patent application pending, detailing 10 different methods to "stiffen a play yard mattress pad before the mattress is used in a play yard bassinet accessory."

**Response:** This comment has been addressed in the final rule on the safety standard for play yards. The Commission stated that the concern regarding the means of stiffening a mattress pad is no longer an issue for the play yard rule because the play yard bassinet accessory misassembly requirement no longer applies to mattress support rods or any other methods that might be used to stiffen a mattress pad. Instead, the play yard rule focuses only on accessory attachment components that attach the bassinet accessory to the play yard. Moreover, the bassinet standard, which addresses mattress flatness, does not require a specific design to pass the standard, and a bassinet can meet the mattress-flatness test in a variety of ways without necessarily implicating patented technology. 78 FR 50333.

#### **5. Requirements for Stability of Removable Bassinet Beds**

**Comment:** One commenter stated that adding the removable bassinet bed stability requirement is premature. The commenter stated the belief that the requirement should be removed from the regulation and that ASTM should be allowed to continue work on this issue.

**Response:** This comment has already been addressed in the Commission’s final consumer product safety standard for bassinets and cradles, which likewise would apply to bedside sleepers with a removable bed.

Specifically, the Commission has provided manufacturers with options to meet the removable bassinet bed requirements. The Commission stated that any product containing a removable bassinet bed with a latching or locking device intended to secure the bassinet bed to the base/stand shall comply with at least one of the following: (1) the base/stand shall not support the bassinet bed (*i.e.*, the bassinet bed falls from the stand and contacts the floor or the base/stand collapses when the bassinet bed is not locked on the base/stand); (2) the lock/latch shall automatically engage under the weight of the bassinet bed (without any other force or action) in all lateral positions; (3) the sleep surface of the bassinet bed shall be at an angle of at least 20 degrees from a horizontal plane when the bassinet bed is in an unlocked position; (4) the bassinet/cradle shall provide a false latch/lock visual indicator(s). At a minimum, an indicator shall be visible to a person standing near both of the two longest sides of the product; or, (5) the bassinet bed shall not tip over and shall retain the CAMI newborn dummy. 78 FR 63022.

## **6. Ambiguity in catastrophic failure evaluation**

**Comment:** One commenter objected to the 30°-tilt requirement in the catastrophic failure test. The commenter stated that the requirement is not adequately supported by scientific data and expressed the belief that this test is counterintuitive to the typical design approach by manufacturers of building in redundancies that prevent catastrophic failure.

**Response:** This comment has been addressed in the Commission’s final rule on the safety standard for play yards. Bedside sleepers that are used in the play yard mode must also meet the play yard requirements. In the play yard context, the Commission explained that the catastrophic



failure test is an alternative to the permanent affixture test. The Commission stated that the angle of 30 degrees represents a safety factor of three times the 10 degrees maximum safe sleep surface angle of incline. The Commission noted that CPSC staff, as well as ASTM members, can reconsider the tilt angle requirement during future revisions should evidence be presented indicating that the angle is too small or large. 78 FR 50332.

In addition any built in redundancies in testing have been resolved because bassinet accessory attachment components are addressed in the play yard standard, and because bassinet accessory mattress support rods are addressed in the bassinet standard. The play yard bassinet accessory misassembly requirement in F406-13 now applies to accessory attachment components. Misassembly issues related to mattress support rods are now addressed in the standard for bassinets and cradles. Bassinets with removable mattress support rods are required to be tested both with and without the mattress support rods. The bassinet also must pass the segmented mattress flatness test, with and without the mattress support rods. Accordingly, all known misassembly issues are addressed in either the play yard or the bassinet final standards.

## **6. Proposed Segmented Mattress Flatness**

**Comment:** One commenter urged the CPSC to adopt the ASTM pass/fail criteria for the surface mattress flatness requirement proposed in the Bassinet NPR. The commenter further asserted that the repeated testing to ASTM F2194 surface flatness requirements has shown a tendency toward a lack of repeatability and that an established principle of looking at the mean of several trials should be used.

**Response:** This comment has been addressed in the final rule on the safety standard for bassinets. The Commission determined that mattress flatness requirement is primarily aimed at incidents involving bassinet/play yard combination products that tend to use segmented

mattresses, where seams could pose a suffocation and positional asphyxiation hazard. Under the Commission's pass/fail criteria, a bassinet attachment with a segmented mattress will fail if any tested seam creates an angle greater than 10 degrees. ASTM F2194-13 allowed measured angles between 10 degrees and 14 degrees to pass, as long as the mean of three measurements on that seam is less than 10 degrees. The 14-degree angle was based on an extrapolation of angles formed by dimensions of average infant faces. However, the Commission declined to use the average infant facial dimension as the basis for this requirement. Instead, in the final rule on bassinets, the Commission adopted the smallest users' anthropometrics to set the test requirement of 10 degrees maximum for each measurement taken. In addition, the bassinet final rule exempts from the mattress flatness requirement bassinets that are less than 15 inches across. The Commission found that these products do not pose the hazard the requirement is intended to address, and they are also not wide enough to test using the required procedures and equipment. 78 FR 63023.

## **7. Assembly and Instructions**

**Comment:** One commenter requested that consistency be maintained with previously adopted mandatory regulations regarding assembly instructions and visual indicators as are demonstrated, for example, in the full-size crib requirement (16 CFR part 1219).

**Response:** Although the language in the full-size crib standard (16 CFR part 1219) and the ASTM F2906-13 and ASTM F2194-13 standards is not identical, the Commission finds that the content is sufficiently consistent among the standards regarding assembly instructions and visual indicators to convey the necessary information.

## **8. Attachment Mechanism**

**Comment:** One commenter stated that a gap between the bedside sleeper and an adult bed creates a risk of injury to an infant in both the bedside sleeper and the adult bed. The commenter recommended that CPSC include an attachment mechanism to be composed of only one part that is then attached to the bedside sleeper, as required in the portable children's bed rail standard, ASTM F2085-12. The commenter stated that the attachment mechanism would not need to be permanently attached to bedside sleepers that are also used in other modes without the attachment, but all necessary parts for attachment should be connected to each other, reducing the chance that caregivers will leave key elements out of the attachment process.

**Response:** The CPSC is not aware of any incidents in which an infant became entrapped in a gap between a bedside sleeper and an adult bed with or without missing key elements of the attachment mechanism. There are very few single-mode bedside sleeper products. Most bedside sleepers are multiuse with other modes, such as bassinets and play yards. Although the commenter indicated the attachment would not need to be connected permanently when used in other modes that do not require the attachment, CPSC staff is concerned that the attachment could present a risk of injury, such as strangulation or entrapment with the attachment cord or strap, when not in use. The addition of requirements to prevent entrapment in a gap between the bedside sleeper and the adult bed on very few single-mode bedside sleeper products at the expense of adding potential strangulation or entrapment risks does not appear warranted. At this time, the Commission does not support the inclusion of a requirement for a one-piece attachment device that would need to be installed permanently on single-mode bedside sleepers and also would need to be removable on bedside sleepers with free standing bassinet or play yard use modes.

## **9. Pictograms and Warnings**

**Comment:** One commenter suggested that adding pictograms to the warnings would effectively convey the hazard and avoid language barriers that minimize comprehension of these warning labels. The commenter also stated that the CPSC should add a warning that would advise the caregiver of the danger adult bedding can pose if bedding is allowed to fall into the bedside sleeper.

**Response:** Currently, all bedside sleeper products are required to comply with the marking and labeling requirements of the bassinet standard. Although a well-developed and tested pictogram could increase comprehension, designing effective, well-understood graphics can be difficult. Poor understanding of graphics may cause consumer confusion, the most severe of which is a critical confusion, where the graphic is interpreted to mean the opposite of the intention. Therefore, any warning pictogram should be developed with empirical study and well tested on the target audience. In addition, there are a number of products for which a soft bedding pictogram could be useful, such as bedside sleepers, bassinets, cribs, play yards, inclined sleep products, and others. Because of the increasing number of multimode products, the Commission believes a cross-product ad hoc working group may be the best place to develop such a pictogram and would allow testing and validation of the pictogram. Subject to budgetary and staff resources, CPSC staff would support participation in any such group, and should the need arise, staff will consider future action once such a graphic is developed.

## **10. Effective Date Marking**

**Comment:** One commenter stated that the CPSC should add a marking on products that are manufactured after the effective date so that consumers can clearly identify products that meet the mandatory standard.

**Response:** On February 13, 2013, a final rule implementing *Testing and Labeling Pertaining to Product Certification*, 16 CFR part 1107 (the 1107 rule), became effective. Under the 1107 rule, a manufacturer or importer may label a certified compliant product as “Meets CPSC Safety Requirements.” Because producers are already allowed to label compliant products as such under the 1107 rule, including this option in the bedside sleeper standard would be redundant. Accordingly, the Commission will not require additional markings at this time.

#### **F. Final Rule**

The CPSC is incorporating by reference ASTM F2906-13 because the Commission’s proposed modifications in the NPR have been adopted in ASTM F2906-13, including the requirements and test methods for bedside sleeper accessories missing accessory attachment components and bedside sleeper accessory fabric-sided enclosed openings. In addition, because bedside sleepers are required to be tested to the bassinet standard, and because the Commission recently issued a final rule incorporating the ASTM standard for bassinets with some modifications, codified at 16 CFR part 1218, the references to the voluntary bassinet standard (ASTM F2194) are revised to reflect the current mandatory bassinet standard, 16 CFR part 1218.

Specifically, ASTM F2194 is referenced in sections 5.1, 5.1.1, 7.1 and 8.1. All of the references to ASTM F2194 are replaced with 16 CFR part 1218 as follows:

- 5.1 Prior to or immediately after testing to this consumer safety specification, the bedside sleeper must be tested to 16 CFR part 1218. Multimode products must also be tested to each applicable standard. When testing to 16 CFR part 1218, the unit shall be freestanding, and not be secured to the test platform, as dictated elsewhere in this standard.

- 5.1.1 The bassinet minimum side height shall be as required in 16 CFR part 1218, with the exception of a lowered side rail as permitted in 5.4.
- 7.1 All bedside sleeper products shall comply with the marking and labeling requirements of 16 CFR part 1218.
- 8.1 All bedside sleeper products shall comply with the instructional literature requirements of 16 CFR part 1218.

## **G. Effective Date**

The Administrative Procedure Act (APA) generally requires that the effective date of the rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). Only one commenter addressed the effective date and supported the 6-month effective date proposed in the NPR. To allow time for bedside sleepers to come into compliance with the standard, the bedside sleeper standard will become effective 6 months after publication of a final rule in the *Federal Register*.

## **H. Regulatory Flexibility Act**

### **1. Introduction**

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires agencies to consider the impact of proposed and final rules on small entities, including small businesses. Section 604 of the RFA requires that the Commission prepare a final regulatory flexibility analysis when promulgating final rules, unless the head of the agency certifies that the rule will not have a significant impact on a substantial number of small entities. The final regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

- a succinct statement of the objectives of, and legal basis for, the rule;

- a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- a description of, and, where feasible, an estimate of, the number of small entities to which the rule will apply;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
- a description of the steps the agency has taken to reduce the significant economic impact on small entities, consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the rule, and why each one of the other significant alternatives to the rule considered by the agency, which affect the impact on small entities, was rejected.

## **2. The Market**

Bedside sleepers are typically produced and/or marketed by juvenile product manufacturers and distributors. Currently, there are at least five known manufacturers supplying bedside sleepers to the U.S. market. Four are domestic manufacturers, including one manufacturer that dominates the market. The fifth is a foreign manufacturer who ships products directly to the United States. There may be additional unknown small manufacturers and importers operating in the U.S. market as well.

The Juvenile Products Manufacturers Association (JPMA), the major U.S. trade association that represents juvenile product manufacturers and importers, runs a voluntary

Certification Program for several juvenile products. Under this program, products voluntarily submitted by manufacturers are tested against the appropriate ASTM standard, and only passing products are allowed to display JPMA's Certification Seal.

Currently, JPMA does not have a Certification Program for bedside sleepers, and no firm claims to meet the ASTM voluntary standard. However, three firms supply multimode products, which in one mode, are compliant with the associated ASTM voluntary standard. Two firms claim compliance with the ASTM standard for bassinets; one firm is JPMA-certified as compliant, and the other claims compliance with the ASTM bassinet standard. A third firm supplies play yards that are JPMA-certified as compliant with the ASTM play yard/non-full-size crib standard.

### **3. Other Federal or State Rules**

There are two federal rules that impact the bedside sleeper standard: (1) *Testing and Labeling Pertaining to Product Certification* (16 CFR part 1107); and (2) *Requirements Pertaining to Third Party Conformity Assessment Bodies* (16 CFR part 1112).

Under 16 CFR part 1107, every manufacturer of a children's product that is subject to a children's product safety rule is required to certify, based on third party testing by a CPSC-accepted conformity assessment body (or laboratory), that the product complies with all applicable safety rules. Because bedside sleepers will be subject to a mandatory children's product safety rule, the product will also be subject to the third party testing requirements of section 14(a)(2) of the CPSA.

Under 16 CFR part 1112, the Commission established requirements for the accreditation of third party conformity assessment bodies to test for conformance with a children's product safety rule in accordance with section 14(a)(2) of the CPSA. This rule amends 16 CFR part 1112



to establish the requirements for accepting the accreditation of a conformity assessment body to test for compliance with the bedside sleeper standard.

#### **4. Impact on Small Businesses**

There are four domestic firms known to be marketing bedside sleepers in the United States. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of bedside sleepers is small if it has 500 or fewer employees. Based on these guidelines, all four domestic manufacturers are small. The economic impact on small domestic manufacturers depends on two factors: (1) whether their products are multiuse products and are already in compliance with one or more existing standards; and (2) the proportion of their total sales or revenue that bedside sleepers constitute.

Three of the four domestic manufacturers produce a multiuse product or a product that may be used as a bedside sleeper as well as a bassinet or play yard. These three multiuse products are required to comply with other existing standards, and there is significant overlap between standards. For example, firms that produce multimode bedside sleeper/play yards are already required to comply with the mandatory play yard standard. In addition, these three multiuse products also function as bassinets and will need to comply with the bassinet standard prior to the effective date for the bedside sleeper final rule. If the products comply with applicable standards pertaining to other use modes, these products will require only slight, incremental modifications. Thus, assuming that these multiuse bedside sleeper products comply or will comply with the standards applicable to other use modes, the three producers of multiuse products are unlikely to experience an economically significant impact due to the bedside sleeper draft final rule.

Two of the domestic manufactures rely almost solely on the sales of bedside sleepers, including a bedside sleeper accessory, as their revenue source. This includes one of the firms mentioned above which produces a multiuse product that will need to comply with an existing standard prior to any effective date for the bedside sleeper draft final rule. Again, based on the assumption that this firm's products will comply with other existing standards, the bedside sleeper rule should not result in a significant economic impact on this firm. The second firm, however, produces a product that serves as a standalone bedside sleeper. Staff believes that this firm's standalone bedside sleeper would need several modifications to meet the requirements in the bedside sleeper standard. The firm will need at least two modifications (adding a lowered fourth side and complying with new stability requirements). However, the firm's plans for modifying the product and costs of compliance are unknown. Even if the cost of each modification taken individually is small, total costs of compliance could be modest or high. Because the majority of this firm's revenues is tied to bedside sleepers and assuming that several modifications may be needed to comply with the bedside sleeper standard, this firm is more likely experience an economically significant impact as a result of the bedside sleeper mandatory standard.

Under section 14 of the CPSA, bedside sleepers are also subject to third party testing and certification. Once the new requirements become effective, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing rule, *Testing and Labeling Pertaining to Product Certification* (16 CFR part 1107). Third party testing will pertain to any physical and mechanical test requirements specified in the bedside sleeper final rule; lead and phthalates testing is already required. Third party testing costs are in addition to the direct costs of meeting the bedside sleeper standard.

Based on information from the durable nursery product industry and confidential business information supplied for the development of the third-party testing rule, testing to a single ASTM voluntary standard could cost around \$500–\$600 per model sample. On average, each small domestic manufacturer supplies two different models of bedside sleepers to the U.S. market annually. Therefore, if third-party testing to the requirements in the bedside sleeper standard were conducted every year on a single sample for each model, third-party testing costs associated for each manufacturer would be about \$1,000–\$1,200 annually. Based on an examination of estimates of firms’ revenues from recent Dun & Bradstreet reports, the impact of third-party testing to ASTM F2906–13 is not likely to be economically significant if only one bedside sleeper sample per model is required. However, if more than one sample would be needed to meet the testing requirements, third-party testing costs could have an economically significant impact on two of the small manufacturers (*i.e.*, based on SBA guidelines, staff typically uses 1 percent of gross revenue as the threshold for determining economic significance and testing costs could be 1 percent or more of gross revenue). The exact number of samples needed to meet the “high degree of assurance” criterion as required in 16 C.F.R. part 1107 is unknown.

## **5. Alternatives**

An alternative to the rule would be to set an effective date later than 6 months, which is generally considered sufficient time for suppliers to come into compliance with a rule. Setting a later effective date would allow suppliers additional time to develop compliant bedside sleepers and spread the associated costs over a longer period of time. The Commission finds that a 6-month effective date is adequate for manufacturers to comply with the bedside sleeper standard

because the changes necessary to comply with the standard are not substantial given that most bedside sleepers are also multi-mode products.

## **I. Environmental Considerations**

The Commission’s regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. These regulations provide a categorical exclusion for certain CPSC actions that normally have “little or no potential for affecting the human environment.” Among those actions are rules or safety standards for consumer products. 16 CFR 1021.5(c)(1). The rule falls within the categorical exclusion.

## **J. Paperwork Reduction Act**

This rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The preamble to the proposed rule (77 FR at 73352 through 73353) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. Sections 7 and 8 of ASTM F2906-13 contain requirements for marking, labeling, and instructional literature. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3).

OMB has assigned control number 3041-0160 to this information collection. The Commission did not receive any comments regarding the information collection burden of this proposal. Accordingly, we estimate the burden of this collection of information as follows:

Table 1 – Estimated Annual Reporting Burden

<b>16 CFR Section</b>	<b>Number of Respondents</b>	<b>Frequency of Responses</b>	<b>Total Annual Responses</b>	<b>Hours per Response</b>	<b>Total Burden Hours</b>
1222	5	2	10	1	10

## **K. Preemption**

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as “consumer product safety rules,” thus, implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

## **L. Certification and Notice of Requirements (NOR)**

Section 14(a) of the CPSA imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard or regulation under any other act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Section 14(a)(2) of the CPSA requires that certification of children’s products subject to a children’s product safety rule be based on testing conducted by a CPSC-accepted third party conformity assessment body. Section 14(a)(3) of the CPSA requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children’s product safety rule to which a children’s product is subject. The “Safety Standard for Bedside Sleepers,” to be codified at 16 CFR part 1222, is a children’s product safety rule that requires the issuance of an NOR.

The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 78 FR 15836 (March 12, 2013), which is codified at 16 CFR part 1112 (referred to here as part 1112). This rule became effective on June 10, 2013. Part 1112 establishes requirements for accreditation of third party conformity assessment bodies (or laboratories) to test for conformance with a children's product safety rule in accordance with Section 14(a)(2) of the CPSA. Part 1112 also codifies a list of all of the NORs that the CPSC had published at the time part 1112 was issued. All NORs issued after the Commission published part 1112, such as the bedside sleeper standard, require the Commission to amend part 1112. Accordingly, this rule amends part 1112 to include the bedside sleeper standard in the list with the other children's product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for bedside sleepers would be required to meet the third party conformity assessment body accreditation requirements in 16 CFR part 1112, *Requirements Pertaining to Third Party Conformity Assessment Bodies*. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to the CPSC to have 16 CFR part 1222, Safety Standard for Bedside Sleepers, included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: [www.cpsc.gov/labsearch](http://www.cpsc.gov/labsearch).

CPSC staff conducted an analysis of the potential impacts on small entities of the proposed rule establishing accreditation requirements, as required by the Regulatory Flexibility Act, and the agency prepared an Initial Regulatory Flexibility Analysis (IRFA). *Requirements Pertaining to Third Party Conformity Assessment Bodies*. 77 FR 31086, 31123-26. Specifically, the NOR for the bedside sleeper standard would not have a significant adverse impact on small

laboratories. Based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the bedside sleeper standard. Most of these laboratories already will have been accredited to test for conformance to other juvenile product standards, and the only cost to them would be the cost of adding the bedside sleeper standard to their scope of accreditation. As a consequence, the Commission certifies that the NOR for the bedside sleeper standard will not have a significant impact on a substantial number of small entities.

## **List of Subjects**

### **16 CFR Part 1112**

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

### **16 CFR Part 1222**

Consumer protection, Imports, Incorporation by reference, Infants and Children, Labeling, Law Enforcement, and Toys.

For the reasons discussed in the preamble, the Commission amends 16 CFR chapter II as follows:

## **PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES**

1. The authority citation for part 1112 continues to read as follows:

**Authority:** 15 U.S.C. 2063; Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008).

2. Amend § 1112.15 by adding paragraph (b)(35) to read as follows:

**§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule or test method?**

\* \* \* \* \*

(b) \* \* \*

(35) 16 CFR part 1222, Safety Standard for Bedside Sleepers.

\* \* \* \* \*

3. Add part 1222 to read as follows:

**PART 1222-SAFETY STANDARD FOR BEDSIDE SLEEPERS**

Sec.

1222.1 Scope.

1222.2 Requirements for bedside sleepers.

**Authority:** The Consumer Product Safety Improvement Act of 2008, Pub. L. 110-314, § 104, 122 Stat. 3016 (August 14, 2008); Pub. L. 112-28, 125 Stat. 273 (August 12, 2011).

**§ 1222.1 Scope.**

This part establishes a consumer product safety standard for bedside sleepers.

**§ 1222.2 Requirements for bedside sleepers.**

(a) Except as provided in paragraph (b) of this section, each bedside sleeper must comply with all applicable provisions of ASTM F2906-13, Standard Consumer Safety Specification for Bedside Sleepers, approved on July 1, 2013. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. § 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org/cpsc.htm>. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West



Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

[http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(b) Comply with ASTM F2906-13 with the following changes:

(1) Instead of complying with section 5.1 of ASTM F2906-13, comply with the following:

(i) Prior to or immediately after testing to this consumer safety specification, the bedside sleeper must be tested to 16 CFR part 1218. Multimode products must also be tested to each applicable standard. When testing to 16 CFR part 1218 the unit shall be freestanding, and not be secured to the test platform as dictated elsewhere in this standard.

(ii) 5.1.1 The bassinet minimum side height shall be as required in 16 CFR part 1218, with the exception of a lowered side rail as permitted in 5.4.

(2) Instead of complying with section 7.1 of ASTM F2906-13, comply with the following:

(i) All bedside sleeper products shall comply with the marking and labeling requirements of 16 CFR part 1218.

(ii) [Reserved]

(3) Instead of complying with section 8.1 of ASTM F2906-13, comply with the following:

(i) All bedside sleeper products shall comply with the instructional literature requirements of 16 CFR part 1218.

(ii) [Reserved]

Dated: January 10, 2014

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Todd A. Stevenson,  
Secretary, Consumer Product Safety Commission

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